

## REMARKS

Claims 1, 3-18, 20-24, and 26 are currently pending. Claims 18, 20, and 21 are currently amended. Claim 19 is currently cancelled without prejudice. Claims 2, 25, and 27-53 were previously cancelled without prejudice. No new matter has been added.

Independent claim 18 is amended to incorporate the recitations of dependent claim 19. Applicants therefore submit that no additional searching or further consideration is required by the Examiner.

Claims 20 and 21 are amended to depend from independent claim 18.

No new matter has been added by these amendments.

### *Rejections under 35 U.S.C. § 103*

Claims 1, 3-24, and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hirabayashi et al., "Contact of hydroxyapatite spacers with split spinous processes in double-door laminoplasty for cervical myelopathy," J. ORTHOP. SCI., 4:264-268 (1999) ("Hirabayashi") in view of U.S. Patent No. 6,511,509 to Ford et al. ("Ford"). Applicants submit these rejections should be withdrawn.

Independent claims 1 and 18 recite an implant insertable between first and second bone ends or segments, having first and second bone engaging portions and an inner side region, "wherein the inner side region is angled with respect to each of the bone engaging portions at an angle ranging from about 50 to about 70 degrees." Examiner has repeated stated that Hirabayashi "discloses the development and optimization of implants for double-door laminoplasty, wherein the resulting implants have angled surfaces clearly within the claimed range of 'about 50 to about 70 degrees.'" (Non-Final Office Action mailed January 24, 2006 at 3; Final Office Action mailed May 4, 2006 ("Final Action") at 2).

Hirabayashi describes experiments held using the STSS spacer in laminoplasty applications "to evaluate the contact rate of the STSS spacer with spinous process in patients." (*Id.* at 264). However, although the STSS spacer is shown to be generally trapezoidal in shape (*see* Fig. 1b), Hirabayashi discloses no angles for the STSS implant described therein.<sup>1</sup> Moreover, the purpose of the Hirabayashi study was to determine the *contact* of a specific implant (the STSS) with the spinous process — Hirabayashi does not explicitly or implicitly implicate the *angles* of the STSS implant as having anything to do with achieving this goal. Rather, Hirabayashi states that implant *shape and size* are relevant considerations in achieving sufficient contact between the implant and spinous process,

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<sup>1</sup> Examiner has stated that Hirabayashi "clearly" shows the claimed range of "about 50 to about 70 degrees," but has not demonstrated how the spacers depicted in Hirabayashi disclose this claim limitation.

which are only configurable *after* the spinous process is bisected. (*Id.* at 267-68). Thus, not only is there is no disclosure of angles in Hirabayashi, there is no suggestion or motivation to arrive at angles “ranging from about 50 to about 70 degrees” to optimize the STSS implant. See *In re Antonie*, 559 F.2d 618 (CCPA 1977) (not obvious to modify to optimize when reference did not recognize the result-effective variable).<sup>2</sup>

Independent claims 1 and 18 further recite an implant having “an inner surface defining a substantially hollow portion,...and first and second ends which communicate with said hollow portion.” Examiner has admitted that Hirabayashi does not specifically disclose an implant “having a substantially hollow portion,” but asserts that “it would have been obvious...to combine the basic inventive concept of Hirabayashi with the teachings of Ford to produce the applicants [*sic*] claimed invention.” (Final Action at 2-3).

As stated above, the purpose of the study in Hirabayashi was to determine the *contact* of a specific implant (the STSS) with the spinous process, and more particularly, *to maximize the contact area* by varying the shape and size of the STSS spacer. A score of “excellent” resulted from “complete touch on both sides of the spacer to the spinous process.” (*Id.* at 264). Moreover, “the appropriate size of the spacer must be selected in accordance with the size of the spinous process to obtain higher percentages of excellent or good contact.” (*Id.*). To achieve greater contact, STSS implants were used that had solid, continuous surfaces, and accordingly “contact between the spacer and the spinous process was assessed by measuring the extent of touch of the spacers to the spinous process.” (*Id.* at 265).

Thus, there would be no motivation to modify the Hirabayashi STSS spacer to have “an inner surface defining a substantially hollow portion,...and first and second ends which communicate with said hollow portion,” as doing so would *reduce* the available surface area to create contact between the implant and the spinous process. In fact, such a modification is directly contrary to the teachings of Hirabayashi, which instead expressly teaches to *maximize* the contact area. See *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (as a “general rule,” a reference that teaches away cannot serve to create a *prima facie* case of obviousness). Thus, Hirabayashi cannot be used as the basis of an obviousness rejection of claim 1 or 18.

Ford fails to remedy the deficiencies of Hirabayashi. Although Ford does show implants having hollow portions extending between two ends (*see, e.g.*, Figures 1A-

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<sup>2</sup> Indeed, Examiner points to nothing to support her statement that “Hirabayashi could be modified to include these angles...since discovering an optimum range or workable range only involves routine skill in the art.” (Final Action at 4).

1B), there still exists no motivation to combine Hirabayashi with Ford to arrive at the claimed implants. It is not sufficient merely say motivation comes from knowledge of those having skill in the art — indeed, “[a] statement that modifications of the prior art to meet the claimed limitation would have been ‘well within the ordinary skill of the art at the time the claimed invention was made’ because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references.” MPEP § 2143.01 (citing *Ex parte Levengood*, 28 U.S.P.Q. 2d 1300 (Bd. Pat. App. & Inter. 1993) (emphasis in original)). Examiner understandably has not identified any “objective reason to combine the teachings of the references” because one does not exist.

Accordingly, as Hirabayashi and Ford, either singly or in combination, fail to teach, suggest, or disclose each and every element of claims 1 and 18, the rejections of those claims should be withdrawn. Similarly, as dependent claims 3-17 depend from independent claim 1, and dependent claims 20-24, and 26 depend from independent claim 18, the rejections of those claims should also be withdrawn, for at least that reason.

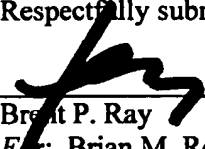
#### **CONCLUSION**

It is believed that claims 1, 3-18, 20-24, and 26 are in condition for allowance. Should the Examiner not agree with Applicants’ position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues.

No fee is believed due for this response. Should any fee(s) be due at this time, please charge such fee(s) to Jones Day Deposit Account No. 503013.

Respectfully submitted,

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